

**Subcommittee on Criminal Justice,
Drug Policy and Human Resources**

Opening Statement of Chairman Mark Souder

**“Human Cloning and Embryonic Stem Cell Research after Seoul: Examining
exploitation, fraud and ethical problems in the research”**

March 7, 2006

Good afternoon, and thank you all for being here.

We are here to examine the controversial research areas of human cloning and embryonic stem cell research in light of the massive scientific scandal in Seoul, South Korea.

This scandal revealed that cloning research widely acclaimed by proponents of human cloning and embryonic stem cell research was a fraud. The scandal also brought to light the disturbing fact that women were paid large sums of money, and female assistants were coerced, to “donate,” if that is the word, their eggs for the stem cell and cloning research, in violation of the Helsinki agreement.¹

Embryonic stem cell research and human cloning have been intense political and societal issues for several years now. Embryonic stem cell research requires the destruction of living human embryos to harvest their stem cells, and research cloning involves the deliberate creation of cloned human embryos for the sole purpose of destroying them to obtain their stem cells.

Proponents of these research areas promise they will result in therapies and cures for a range of maladies and diseases, although there has been little hard, empirical evidence to support these claims. In fact, there are currently no human clinical trials or therapeutic applications using human embryonic stem cells.

And here I will quote British stem cell expert Professor Lord Winston: “One of the problems is that in order to persuade the public that we must do this work, we often go rather too far in promising what we might achieve... I am not entirely convinced that embryonic stem cells will, in my lifetime, and possibly anybody’s lifetime for that matter, be holding quite the promise that we desperately hope they will.”²

¹ WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: Ethical Principles for Medical Research Involving Human Subjects (Adopted by the World Medical Association General Assembly in June, 1964). One of its principles states, “When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.” See <http://www.trepan.com/agreement.html> (last visited March 6, 2006).

² Lecture at Gresham College, June 20, 2005, www.gresham.ac.uk/printtranscript.asp?EventId=347 (last visited March 6, 2006).

In contrast to the lack of any therapeutic applications using embryonic stem cells, adult stem cells have provided therapeutic benefits to human patients for at least 67 diseases and conditions. Nonetheless, even in the absence of therapeutic applications for embryonic stem cells, scientists have been very clear that they seek to use stem cells from cloned human embryos as research tools.

Various critics of research cloning and embryonic stem cell research have raised a myriad of objections to the research:

- The research necessarily requires the destruction of living human embryos (and in the case of cloning, the special creation of embryos to be destroyed for their stem cells).
- The research necessarily requires a large number of eggs, likely leading to the exploitation of women in order to obtain their eggs for research.
- Advocates of research cloning/embryonic stem cell research have created unjustified “hype” of the research that is not supported by current science, but plays on the hopes of suffering patients.

These criticisms were borne out through the cloning research conducted by Dr. Hwang [*pronounced wong*], whose two groundbreaking papers were retracted in January by the peer-reviewed journal that initially published them. In addition to admitting that he deliberately fabricated data, Hwang has also admitted that he had lied about the circumstances under which he obtained eggs for his research, and that in fact he had used eggs from junior scientists in his laboratory - a violation of the Helsinki declaration - as well as from paid donors.

Skeptics of cloning and embryonic stem cell research consistently *warned* that the sheer volume of eggs needed to pursue this line of research would make it untenable, and virtually *invite* ethical lapses by fueling the temptation to exploit women for their eggs. Hwang’s research proves those fears. He initially claimed that he had used only 185 eggs from female donors, which the scientific community agreed was astonishingly low. But investigators now believe that more than 2,200 eggs were obtained from 119 women.

Some donors who have since reported they were in desperate need of money when they were offered and paid more than \$1400 for their eggs. And according to the South Korean National Bioethics Committee, the women had not been properly informed about the risks to their health: 15-20 percent of those women developed ovarian hyperstimulation syndrome.

This scientific scandal is not an isolated incident of fabrication, without real application to U.S. research efforts. Rather, it highlights the serious, inherent potential problems with research cloning and embryonic stem cell research, including but not limited to: exploitation, fraud, and coercion. The incident is a siren warning against proceeding in these research areas without *most cautiously* examining the societal costs necessarily associated with it. It would be quite disingenuous to say otherwise.

Dr. Hwang was not a rogue scientist operating on the fringes of his field with no oversight. He operated in an environment that proponents of cloning and embryonic stem cell research would like to see adopted in the United States:

- Dr. Hwang enjoyed the full support of his government, which vigorously promoted his research and funded it with tens of millions of dollars.
- Dr. Hwang also enjoyed enormous popular support and he had agreed to conduct his research under accepted ethical protocols.
- Dr. Hwang suspended his research until ethics laws were enacted by the South Korean government to demonstrate his willing compliance with ethical standards.
- Dr. Hwang's research was conducted with the approval of two separate Institutional Review Boards.

Nonetheless, Dr. Hwang's actions represent the fulfillment of every warning dismissed by proponents of research cloning and embryonic stem cell research: thousands of eggs were obtained through payments and coercion; many women suffered terrible side-effects after they were not properly informed of the risks; not a single embryonic stem cell line was obtained for the tens of millions of dollars in government funds that were invested in the research; anxious patients were misled about the research potential.

As stem cell researcher Ron McKay said about the hype involved with embryonic stem cell research and distortions that are not aggressively corrected by scientists – quote – “To start with, people need a fairy tale. Maybe that's unfair, but they need a story line that's relatively simple to understand.”³

Our examination today will include an overview of current federal policies relating to these research areas. In particular, we'll hear what, if any, extra protections exist in the United States that would prevent the type of widespread fraud or exploitation apparent in the Hwang research. Also of special interest to the Subcommittee are the huge federal grants that have been awarded to University of Pittsburgh researcher Gerald Schatten, who was initially a co-author on one of Hwang's fraudulent papers.

We'll also hear from scientists, ethicists, women's advocates, and a patient advocate discuss these research areas and the known problems associated with them.

Our first panel today consists of James F. Battey, Chair of the NIH Stem Cell Task Force, and Director of the National Institute on Deafness and Other Communication Disorders; Bernard Schwetz, Director of the Office for Human Research Protections; and Chris B. Pascal, Director, Office of Research Integrity.

The second panel consists of Dr. Richard Chole, [*pronounced kōl*], Lindberg Professor and Chairman, Department of Otolaryngology, Washington University School of Medicine, St. Louis; Ms. Judy Norsigian [*pronounced nor-see-jin*], Executive Director, Our Bodies Ourselves; Co-author of the book "Our Bodies, Ourselves"; Ms. Diane Beeson, Professor Emerita, Department of Sociology and Social Services, California State University, East Bay; Mr. Richard Doerflinger, Deputy Director, Secretariat for Pro-Life Activities, U.S. Conference of Catholic Bishops; Ms. Debra Mathews, Assistant Director for Science Programs, The Phoebe R. Berman Bioethics Institute; and Mr. Joe Brown, Parkinson's Action Network State Coordinator of Texas.

³ Weiss, R., “Stem Cells An Unlikely Therapy for Alzheimer's,” The Washington Post, June 10, 2004, p. A3.